

July 19, 2004

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Dr. C. W. Jameson  
National Toxicology Program  
Report on Carcinogens  
79 Alexander Drive  
Building 4401, Room 3118  
P.O. Box 12233  
Research Triangle Park, NC 27709

Dear Dr. Jameson:

ORC Worldwide is pleased to submit these comments on the inclusion of Metalworking Fluids (MWF) in the "National Toxicology Program Call for Public Comments on 21 Substances, Mixtures and Exposure Circumstances Proposed for Listing in the Report on Carcinogens, Twelfth Edition" that is scheduled for publication in 2006.

ORC is an international management and human resources consulting firm whose Washington, D.C. office has for over 30 years specialized in providing a wide array of occupational safety and health consulting services to American businesses. Currently, over 150 large (mostly Fortune 500) companies in diverse industries are members of ORC's Occupational Safety and Health Groups. The focus of these groups is to promote effective occupational safety and health programs and practices in business, to facilitate constructive communications between business and government agencies responsible for establishing national occupational safety and health policy, and to advocate responsible business positions to the regulators.

The activities of ORC's Occupational Safety and Health Groups are based on the premise that providing safe and healthful working conditions is the mutual concern of employers, employees and government agencies. A list of companies that are members of ORC's Occupational Safety and Health Groups is attached to these comments and, as described more fully below, many of these companies have provided substantial information, opinion and advice to ORC in the development of its comments. However, these comments are solely those of ORC and may differ from the views and comments of individual member companies.

ORC has led a consortium of organizations and member companies, the ORC Metal Removal Fluids Task Force, since 1997. The Task Force has provided expertise to

government bodies, commented on rulemaking proceedings, and produced a respected set of guidance, entitled "Management of the Metal Removal Fluid Environment: A Guide to the Safe and Efficient Use of Metal Removal Fluids." The document contains state of the art recommendations from industry experts for all aspects of managing and maintaining MWF.

The classification of substances as "Metalworking Fluids" describes a function rather than a specific (or even generic) chemical composition, and therefore lacks meaning in the context of both characterizing and preventing exposure to a potential carcinogen(s), because metalworking fluids are complex mixtures of a variety of substances. Metalworking fluids may contain mineral oils, vegetable oils, synthetic oils, emulsifiers, anti-weld agents, corrosion inhibitors, extreme pressure additives, buffers, biocides and other additives. They are most frequently used to cool and lubricate tools and working surfaces in a variety of industrial machining and grinding operations.

Unlike other mixtures that NTP will evaluate, however, such as asphalt fumes or *Aristolochia* that are inherent in the mixtures and of a predictable composition, metalworking fluid mixtures are formulated by manufacturing engineers to achieve a specific purpose. Each component is added to impart a desired characteristic to the fluid. There may be several chemicals in a particular component category from which an engineer can select, some with fewer occupational exposure risks than others. Hundreds of different chemicals can be found in MWF and thousands of brand name MWFs are available. In this sense, the term "metalworking fluids" compares with the term "paints," with equal variety in possible components and their associated hazards.

The criteria that NTP uses for evaluating substances to include in its Report on Carcinogens are not applicable to metalworking fluids. Studies claiming evidence of limited carcinogenicity in humans have been published, however, the specific substances to which employees were exposed were never identified, and therefore it is not possible to understand what the outcomes mean from either a qualitative or quantitative standpoint.

Recent epidemiologic studies of cancer in workers exposed to metalworking fluids in the 1960s and 1970s have shown limited associations between exposure to straight oils and rectal and laryngeal cancer, and soluble oils and laryngeal cancer. It is, however, not possible to apply the experience of those workers to current conditions, since the types and formulations of metalworking fluids in use today differ substantially from those to which the workers in the studies were exposed. Additionally, manufacturing processes were less specialized and segregated than today, confounding exposures.

In the past, straight and soluble oils were likely to have been unrefined and thus may have contained known carcinogens such as poly nuclear aromatic hydrocarbons (PAHs). Oils in use today are highly refined and thus carcinogens are much less likely to be present in hazardous amounts. In their article "Petroleum Mineral Oil Refining and

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Evaluation of Cancer Hazard," published in the November 2003 issue of Applied Occupational and Environmental Hygiene, Carl R. Mackerer, Larry C. Griffis, John S. Grabowski, and Fred A. Reitman stated "...test results of currently manufactured base oils ...illustrate the general lack of cancer hazard for the base oils now being manufactured."

In his article "Epidemiologic Evidence on the Carcinogenicity of Metalworking Fluids," published in Applied Occupational and Environmental Hygiene in November 2003, Dr. David A. Savitz commented:

"The agents used and hygienic conditions have changed completely over the past 50 years, so that the more remote historical experience is not directly applicable to the present. Studies of earlier exposure only indicate that at least some of the chemicals in metalworking fluids used previously were capable of causing cancer. The specific agents responsible, the impact of changes in the industry, and the timing of those changes in relation to cancer risk are not well understood.

"The exposure is a changing, complex, highly variable class of chemical agents that share an industrial application, as well as additives and by-products. Thus, it is very difficult to extrapolate findings from one setting to another or to confidently relate evidence from toxicology (which must select specific agents for assessment) to human experience. Because of the diversity of agents, it is difficult to quantify exposure appropriately to examine in relation to risk of disease."

In light of current knowledge about the minimal potential for cancer risk posed by current metalworking fluid formulations, testing of individual MWF formulations will have limited value in improving workplace health and safety. Most importantly, any listing NTP makes relative to MWFs should focus on the evaluation of the carcinogenic potential of the specific components of MWFs, not the finished formulations themselves.

In the absence of studies that identify the agents of concern, or that can be applied to current workplace environments, there is insufficient evidence of carcinogenicity at this time to justify inclusion of "Metalworking Fluids" as a substance or mixture in the 2006 NTP Report on Carcinogens. The ORC Metal Removal Fluid Task Force believes that further evidence must be gathered regarding current, relevant exposures before such a listing can be justified. The ORC MRF Task Force believes that a focused, systematic approach to identifying constituents of concern and selecting those specific substances for evaluation is most likely to produce results that can be acted upon by users and formulators to minimize occupational health risk. The best use of time and resources involves:


- Screening specific categories of MWF components for potential risk,

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- Selecting a subset of components that show potential risk for further evaluation.

Our members stand ready to advise NTP regarding future studies of metalworking fluids and their carcinogenic potential.

Sincerely,

A handwritten signature in black ink, appearing to read 'Frank A. White', written over a horizontal line.

Frank A. White  
Vice President  
ORC Worldwide